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FORM PTO-1390 (REV 11-98) — U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	US APPLICATION NO (If known, see 37 CFR 1.5)
013258.0172	09/242215

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US97/13379	04 AUGUST 1997	09 AUGUST 1996

TITLE OF INVENTION
COMPOSITIONS OF PLANT CARBOHYDRATES AS DIETARY SUPPLEMENTS

APPLICANT(S) FOR DO/EO/US
McAnalley et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [X] This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. [X] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] has been transmitted by the International Bureau.
   c. [X] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [ ] A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. [X] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [X] have been transmitted by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.
8. [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [X] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. [X] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [X] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [X] A FIRST preliminary amendment.
    [ ] A SECOND or SUBSEQUENT preliminary amendment.
14. [ ] A substitute specification.
15. [ ] A change of power of attorney and/or address letter.
16. [ ] Other items or information:

U.S APPLICATION NO (if known see 37 CFR 1 5)	INTERNATIONAL APPLICATION NO PCT/US97/13379	ATTORNEY'S DOCKET NUMBER 013258.0172

17. [X] The following fees are submitted:	CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$970.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$840.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$760.00**		
International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$670.00**		
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) **$96.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 670.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ -0-	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	17 - 20 =	0	X **$18.00**	$ -0-	
Independent claims	1 - 3 =	0	X **$78.00**	$ -0-	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$260.00**	$ -0-	

TOTAL OF ABOVE CALCULATIONS =	$ 670.00	
Reduction of 1/2 for filing by small entity, if applicable. A Small Entity Statement must also by filed (Note 37 CFR 1.9, 1.27, 1.28).	$ -0-	
SUBTOTAL =	$ 670.00	
Processing fee of **$130.00** for furnishing the English translation later than [ ]20 [ ]30 months from the earliest claimed priority date (37 CFR 1.492(f)). +	$ -0-	
TOTAL NATIONAL FEE =	$ 670.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +	$ 40.00	
TOTAL FEES ENCLOSED =	$ 710.00	
	Amount to be: refunded	$
	charged	$

a. [XX] A check in the amount of $ 710.00 to cover the above fees is enclosed.

b. [ ] Please charge my Deposit Account No. _____ in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [XX] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 01-0657 . A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

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31,213
REGISTRATION NUMBER

Patent
Attorney Docket
No. 013258.0172

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

MCANALLEY ET AL.

Group Art Unit: N/A

Serial No. N/A

Based upon International Application
Serial No. PCT/US97/13379

Examiner: N/A

Filed: FEBRUARY 8, 1999

For: COMPOSITIONS OF PLANT CARBOHYDRATES AS DIETARY SUPPLEMENTS

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

"Express Mail" Mailing Label Number EL210446946US, Date of Deposit February 8, 1999. I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, DC 20231.

Ellen Lovelace
Type or Print Name

Ellen Lovelace
Signature

Assistant Commissioner
for Patents
Washington, D.C. 20231

Sir:

PRELIMINARY AMENDMENT

Prior to initial examination on the merits, please amend the above-application as follows:

IN THE CLAIMS

Please cancel claims 2-5 without prejudice or disclaimer.

Please amend claims 1, 6-8, 12-13 and 15-16 as follows:

1. (Amended) A dietary supplement for providing nutritional product saccharides in monomeric, oligomeric or polymeric and derivatized or underivatized form, which saccharides

are essential components of glycoproteins in a mammal, said dietary supplement comprising a composition consisting [essentially] of nutritionally effective amounts of:

at least one saccharide [, in monomeric, oligomeric or polymeric and derivatized or underivatized form,] selected from a first [the] group of saccharides consisting of:

galactose, glucose, mannose, xylose and acetylated mannose; and

at least one saccharide [, in monomeric, oligomeric or polymeric and derivatized or underivatized form,] selected from a second [the] group of saccharides consisting of:

N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, galacturonic acid, iduronic acid, and arabinogalactan.

6. (Amended) A dietary supplement according to claim 1 [, 2, 3, 4, or 5] wherein at least one of said saccharides is provided in oligomeric or polymeric form as found in at least one of:

gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, aloe vera extract, gum ghatti, starch, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate, sucrose, acetylated polymannose, maltose, glucan, lentinan, mannan, levan, hemi-cellulose, inulin, fructan, and lactose.

7. (Amended) A dietary supplement according to claim 1 [, 2, 3, 4, or 5] further comprising a nutritionally effective amount of dioscorea complex.

8. (Amended) A dietary supplement according to claim 1 [, 2, 3, 4, or 5] further comprising a nutritionally effective amount of a blend consisting of ripened and freeze-dried and powdered raw fruits and vegetables.

12. (Amended) A dietary supplement according to claim 1 [, 2, 3, 4, or 5] further comprising a nutritionally effective amount of melatonin.

13. (Amended) A dietary supplement according to claim 1 [, 2, 3, 4, or 5] further comprising an effective amount of a saccharide bioabsorption aid.

15. (Amended) A dietary supplement according to claim 1 [, 2, 3, 4, or 5] further comprising nutritionally effective amounts of a dioscorea complex and a blend consisting of ripened and freeze-dried and powdered raw fruits and vegetables.

16. (Amended) A dietary supplement according to claim 1 [, 2, 3, 4, or 5] further comprising nutritionally effective amounts of non-toxic vitamins and minerals.

Please add new claims 18-21 as follows:

-- 18. A dietary supplement according to claim 1, wherein said composition comprises at least two saccharides selected from the second group of saccharides. --

-- 19. A dietary supplement according to claim 1, wherein said composition comprises at least three saccharides selected from the second group of saccharides. --

-- 20. A dietary supplement according to claim 1, wherein said composition comprises at least four saccharides selected from the second group of saccharides. --

-- 21. A dietary supplement according to claim 1, wherein said composition comprises at least five saccharides selected from the second group of saccharides. --

REMARKS

Claims 1 and 6-21 are pending herein. Original claims 2-5 have been canceled in favor of new claims 18-21. Claims 1, 6-8, 12-13 and 15-16 have been amended, more particulary, to point out, the claimed subject matter. It is respectfully submitted that pending claims 1 and 6-21 are in

full compliance with the broad dictates of 35 U.S.C. § 112. Early and favorable consideration of claims 1 and 6-21 are respectfully requested.

Respectfully submitted,

Date: 8 February 1999

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#200282 v1; 013258.0172

Compositions of Plant Carbohydrates As Dietary Supplements

FIELD OF THE INVENTION

This invention pertains to the field of dietary supplements and nutritional support for promotion and maintenance of good health. More specifically, the invention relates to compositions of carbohydrates as dietary supplements that are essential for the production of correctly structured and, therefore, properly functioning glycoproteins.

DESCRIPTION OF THE PRIOR ART AND OTHER INFORMATION

The term mucus was first used in the 1700s. By 1805, Bostok realized that mucus was composed of protein that differed from albumin and gelatin. In 1865, Eichwald showed that mucins contained carbohydrate moieties. In 1877, Hoppe-Seyler discovered that mucins were high in sialic acid content. In 1882, Landwehr showed that plant gums, a type of mucin, contain more than one monosaccharide. With the advent of more modern methods, these monosaccharides were isolated and characterized. In 1888. Harmarsten showed that the saccharides in mucins were joined by a covalent bond; Harmarsten was the first to use the term "glykoproteide" (or glycoprotein in English). Fischer and Leuchs discovered high concentrations of mannose in mucus in 1902. Hayworth, in 1939, discovered N-acetylglucosamine and Bierry discovered galactose in 1930. Meyer discovered fucose in 1958 (Gottschalk, Glycoproteins, 1972).

Proteins were originally thought to be the primary "communication" molecules of the body. The biotechnology revolution began as an attempt to create new drugs based upon proteins which are made up of various combinations of amino acids. However, since amino acids can only bind to each other through an amide bond, the number of secondary configurations possible with proteins is limited. Indeed, only one secondary configuration is possible per dipeptide.

However, many more functions are performed by the body than can be accounted for by the number of molecular configurations possible with proteins. Several years ago a theoretical mathematician calculated the number of configurations possible with proteins and discovered that another mechanism, yet unknown, had to be responsible for performing most of the communication functions of the body. It is now known that this mechanism involves carbohydrates.

In contrast to the simpler proteins, more molecular configurations are possible with the more complex carbohydrate molecule, e.g., a hexose has six chiral centers each of which has

two isomeric forms and each of which has a hydroxyl group as a binding site for other molecules. Thus, while only 24 oligopeptide configurations are possible with four amino acids, more than 100,000 different oligosaccharide configurations are possible with four sugars (Stryer et al., Biochemistry, 1995; p 477).

Science has recently shown that glycoproteins play a key role in all cellular communication. Many of the cytokines, i.e. cellular messenger agents, do not function properly without an attached glycosyl moiety. The body hydrolyzes complex polysaccharides such as plant carbohydrates into various monosugars and restructures them into oligosaccharides that are then used by the body to build the glycoproteins required by cytokines for cellular communication and, thus, for good health.

With the advent of improved analytical techniques and more powerful computers, characterization of glycoproteins increased rapidly after the 1960s. By the mid 1980s, the mechanism of the orderly synthesis of glycoproteins in the endoplasmic reticulum and Golgi apparatus had been determined. The actual oligosaccharide conformations of many glycoproteins is now known.

Increasing interest in glycobiology has been precipitated by recent findings that cell surface carbohydrates are critically involved in cell adhesion and, thus, in cell-cell interaction. Specifically, three new mechanistic concepts have been discovered. First, structural studies in glycoproteins and glycolipids have revealed the existence of carbohydrates which are unique to certain cell types. This concept is crucial to understanding cell surface carbohydrates as cell-type specific recognition molecules.

A second concept was developed from new information regarding lectins, which have sugar-binding proteins. In the 1970s it was learned that glycoproteins were removed rapidly from the blood when their sialic acid, i.e. N-acetylneuraminic acid, containing branches were removed. Further studies revealed that this rapid clearance was caused by asialoglycoproteins binding to lectins that recognize terminal galactose. Once animal cells were known to have lectins, a large number of lectins were characterized, and a dedicated section in the amino acid sequence that is responsible for the carbohydrate recognition domain in the lectins was discovered. This discovery was critical to understanding carbohydrate-binding capability in cell-cell interactions. Thus, cellular communication was recognized at the molecular level.

The third concept resulted from studies regarding the isolation and characterization of the glycosyltransferases that form carbohydrates. These studies showed that carbohydrate

moieties are usually built one by one, and each reaction is carried out by a glycosyltransferase that forms only a specific linkage. The advent of molecular biology in this field has enabled scientists to manipulate carbohydrate expression and study glycoprotein function.

Based on critical advances in this field, the most recent studies demonstrated that oligosaccharides uniquely present in leukocytes act as ligands for adhesive molecules in endothelia and platelets. When these adhesive molecules, known as selectins, were cloned, it was discovered that they contained carbohydrate recognition domains. Thus, studies on cell-type specific carbohydrates and animal lectins corroborated each other. Moreover, these studies were preceded by the findings that lymphocyte-endothelial interaction is dependent upon carbohydrates.

Given the above, research directed toward the synthesis of drugs that would correct malformation of glycoproteins on cell surfaces began. After the carbohydrate ligand sialyl-Le^x was identified, pharmaceutical companies soon synthesized it for therapeutic purposes. This line of research has since become much easier because enzymatic synthesis of carbohydrates is now possible thanks to the availability of glycosyltransferases generated by cloned cDNAs (Fukuda et al., Glycobiology, 1994).

The synthesis of all proteins and glycoproteins is controlled by somatic genes embodied in the chromosomes of a cell. The coding information expressed in nucleic acids (DNA) controls all cellular functions, including general body defense, regeneration, remodeling and healing. Though DNA provides the blueprint, the cellular components cannot be built correctly without the required building blocks. As discussed above, cytokines are key components used for intracellular instruction to carry out the body's vital functions. However, many cytokines do not function properly without an attached glycosyl moiety.

Table 1 lists some of the known physiological functions served by glycoproteins. Table 2 lists some of the specific known functions that the oligosaccharide branches or chains of glycoproteins perform.

Table 1. Some known functions served by glycoproteins:

Function	Glycoproteins
Structural molecule	Collagens
Lubricant and protective agent	Mucins

Transport molecule	Transferrin, ceruloplasmin
Immunologic molecule	Immunoglobulins, histocompatibility antigens
Hormone	Chorionic gonadotropin, thyroid-stimulating hormone (TSH)
Enzyme	Various, e.g., alkaline phosphatase
Cell attachment-recognition site	Various proteins involved in cell-cell (e.g., sperm-oocyte), virus-cell, bacterium- cell, and hormone-cell interactions
Interact with specific carbohydrates	Some lectins

Table 2. Some known functions of the oligosaccharide chains of glycoproteins:

* Modulate physicochemical properties, e.g., solubility, viscosity, charge, and protein denaturation
* Protect against proteolysis from within and outside the cell
* Affect proteolytic processing of precursor proteins to smaller products
* Are involved in biologic activity, e.g., of human chorionic gonadotropin (hCG)
* Affect insertion of protein into membranes, intracellular protein migration, and protein sorting and secretion
* Affect embryonic development and differentiation
* Affect metabolism
* May affect sites of metastases selected by cancer cells

In summary, various processes of the cell are regulated or affected by correctly structured and, therefore, properly functioning glycoproteins.

Despite the above discussed current scientific knowledge concerning the importance of glycoproteins to cell-cell communication and the importance of carbohydrates in the formation of glycoproteins, and despite the fact that diet is the source of a majority of carbohydrates, the fields of glycobiology and nutrition have never been adequately investigated together. Although current nutrition textbooks stress the importance of essential vitamins, minerals, proteins (amino acids) and fats in great detail, sugars are currently recognized only as a source of energy (Shils et al., 1994)--not as substances essential to glycoprotein production for good health. For example, Shils et al. disclose that the principal sources of dietary carbohydrates are: 1) maize, rice, wheat, and potato which yield starches comprising glucose; 2) sugar cane and beet sugar which yield fructose and glucose; and 3) milk which yields galactose and glucose (Shils et al., Modern Nutrition in Health and Disease, (1994)).

By way of contrast, Harper's Biochemistry (Murray et al., 1996) lists eight and Principles of Biochemistry, Vol II (Zubay et al., 1995) lists eleven monosaccharides commonly found in the oligosaccharide chains of cellular glycoproteins. Thus, of the approximate 200 monosaccharides found in nature, these eleven are believed to be important toward maintaining good health in mammals.

These eleven saccharides include galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose (Murray et al., Harper's Biochemistry, 1996) as well as iduronic acid, arabinose and glucuronic acid, (Zubay et al., Principles of Biochemistry, Vol II, 1995). The structures of these carbohydrates are disclosed in Stryer's Biochemistry (Stryer, 1995) and the Merck Index, 12th Edition, 1996.

Recognizing this, scientists are currently trying, as yet with limited success, to synthetically attach glycosyl moieties to cytokines and other proteins. In fact, NIH has launched a project to develop methods to synthesize the glyco portion currently missing from their genetically engineered proteins. These synthetically produced cytokines have so far demonstrated disappointing results. Many challenges remain in this area. Scientists must first learn: 1) how to synthesize the glyco portion, 2) how to attach the glyco portion to the protein, and then 3) how to get the correct glycoproteins in the right concentrations to the right places in the body so as to facilitate good health.

For centuries, people of diverse cultures from around the world have utilized plants and herbs in the treatment of a wide variety of disorders in mammals. Specifically, formulations including poultices, teas, powders, pastes, extracts, plant or herb parts, plant or herbal extracts, lotions, creams, salves, troches, and others have been used. It is also now well recognized that much of the world's farm lands have been depleted of essential minerals required to sustain life, thus requiring the widespread use of vitamin, mineral and dietary supplements. A recent discovery concerns the importance of plant chemicals (phytochemicals) that are found in vine-ripened fruits and vegetables but are not found in those that are not vine-ripened. To provide these necessary, yet undefined, phytonutrients or phytonutritionals, as defined below, to the diet, some companies have begun supplying dietary supplements of freeze-dried, vine-ripened fruits and vegetables.

Nutritionists have developed hundreds of dietary supplement formulations in an effort to provide essential dietary components and facilitate and promote good health in mammals. However, fraudulent product claims regarding the treatment of physiological disorders are pervasive in the industry, and modern farming methods which focus on volume rather than nutritional value of crop production have led to crops having reduced dietary value that are missing essential dietary components.

Despite the extremely large number of dietary supplements available on store shelves today, the dietary needs of humans are still not being met. Many of such commercially available dietary supplements do not appear to provide any significant nutritional benefit. The present inventors believe such prior products suffer any one or more of the following disadvantages: a) they do not include the correct nutritional product(s); and b) their nutritional products are not well absorbed by a person taking them.

Thus, while scientists are beginning to recognize that other phytochemicals are required for good health, and others have previously recognized the utility of plants and herbs in the treatment of disorders, none of the known art suggests or discloses the invention as claimed herein. A need remains for non-pharmaceutical based dietary supplement formulations which provide essential saccharides that are the building blocks of glycoproteins and which promote good health in mammals.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a dietary supplement which promotes good health by providing to a mammal essential saccharides which are the building blocks of glycoproteins.

It has now been demonstrated herein by the present inventors that inclusion of these essential saccharides, as by supplementation of a diet with a dietary supplement containing the same, in the diets of mammals promotes good health. Although not intended to be limited to a particular mechanism of action, these essential saccharides are believed to be absorbed into the mammal's body and utilized in the formation of glycoproteins. By so providing these essential saccharides, the mammal's body does not have to spend energy unnecessarily catabolizing these essential saccharides and can therefore spend its energy providing for other physiological needs such as enhancement of the immune system to ward off, combat and/or ameliorate a wide range of physiological disorders.

Thus, the present invention overcomes the disadvantages and drawbacks of the prior art. One aspect of the present invention is directed to the use of various compositions of carbohydrates, i.e., glyconutritionals or glyconutrients, as dietary supplements which supplement a mammal's diet with sugars essential to glycoprotein and/or glycolipid production and thereby promote good health. In one embodiment, the present invention is directed to nutritional supplements including a defined amount of at least one of the eleven carbohydrates that are essential for the production of correctly structured and, therefore, properly functioning glycoproteins and/or glycolipids in a mammal. While some of these eleven sugars are readily available in common food sources, others are quite rare.

Accordingly, a first embodiment of the invention provides a dietary supplement for providing nutritional product saccharides which are essential components of glycoproteins in a mammal, said dietary supplement comprising a nutritionally effective amount of at least one saccharide, in monomeric, oligomeric or polymeric and derivatized or underivatized form, selected from the group consisting of:

galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, xylose, arabinose, glucuronic acid, galacturonic acid, iduronic acid, arabinogalactan, acetylated mannose, glucosamine and galactosamine.

In other embodiments of the invention, the dietary supplement comprises nutritionally effective amounts of at least two, at least three, at least four, at least five, at least six, at least seven, at least eight, at least nine, at least ten or at least eleven saccharides, in monomeric, oligomeric or polymeric and derivatized or underivatized forms selected from the above listed group. Since some of these saccharides have ionizable groups, the invention contemplates all known non-toxic salt forms thereof.

The monomeric, oligomeric or polymeric and derivatized or underivatized forms of these saccharides can be obtained from a wide variety of sources, such as for example, gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, aloe vera extract, gum ghatti, starch, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate, sucrose, acetylated polymannose, maltose, glucan, lentinan, mannan, levan, hemi-cellulose, inulin, fructan, and lactose.

Other embodiments of the invention can comprise phytochemicals or phytonutritionals derived from ripened and freeze-dried fruits and vegetables, dioscorea complex, herbal extracts, herbal body-toning agents, beta sitosterol, melatonin, soy lecithin, vitamins, or minerals.

In another embodiment of the present invention, the compositions include predigested forms of at least one of the eleven essential carbohydrates. This can include one or all of the following: 1) physical digestion such as shearing or treatment with ultrasound, 2) chemical digestion such as enzymatic digestion, and acid or base hydrolysis, and 3) biological digestion with microbes such as bacteria, fungi or molds.

In another aspect, the present invention is a dietary supplement for the modification of behavior in alcohol dependent mammals comprising nutritionally effective amounts of the natural and/or synthetic monomeric, oligomeric and/or polymeric forms of acetylated mannose, gum ghatti, gum tragacanth, glucosamine, corn starch and arabinogalactan. In a particular embodiment, the dietary supplement will reduce the craving for alcohol in an alcohol dependent mammal being administered the supplement. In another particular embodiment, the dietary supplement will improve the overall well being of the alcohol dependent mammal by reducing at least one of depression and anger or increasing at least one of cognition, energy and positive outlook.

In yet another aspect, the present invention is a dietary supplement for the reduction of undesired side-effects in mammals receiving biologically effective agents that cause said side-effects, said dietary supplement comprising nutritionally effective amounts of the natural and/or synthetic monomeric, oligomeric and/or polymeric forms of acetylated mannose, gum ghatti, gum tragacanth, glucosamine, corn starch and arabinogalactan. In a particular embodiment, the dietary supplement will reduce the undesired side-effects of central nervous system drugs. In a more particular embodiment, the dietary supplement will reduce the undesired side-effects of methylphenidate in a mammal suffering from attention-deficit hyperactivity disorder and receiving methylphenidate.

DETAILED DESCRIPTION

The body of a mammal hydrolyzes or metabolizes complex polysaccharides, such as plant carbohydrates, into various monosaccharides and subsequently forms oligosaccharides therefrom that are then used by the body to build the glycoproteins required by cytokines for cellular communication.

As used herein, the term "phytochemical" refers to plant synthesized molecules, found in food, or plant tissue in a complex organic matrix, which are minimally altered by processing from how they occur in nature. As used herein, the term "nutraceutical" refers to a non-toxic, nutrient of plant, mineral or animal origin, that has health promoting activity and that can be standardized and supplied as a dietary supplement to improve the nutritional quality of a balanced general diet. A nutraceutical is also a glyconutrient or phytonutrient.

As used herein, the terms "glyconutritional" or "glyconutrient" refer to complex carbohydrates or saccharides or simple sugars that are synthesized in nature and are necessary for the biochemical synthesis of various classes of communication and signal molecules that may be free in interstitial cellular fluids, active in cell to cell communication (i.e., cytokines, growth factors, etc.), or constitute the molecular configuration comprising foci of highly specific molecular activity of cell membranes (i.e., receptor sites, ion-transport channels, antigenic identification, and the like).

As used herein, the terms "phytonutritional" or "phytonutrient" refer to naturally synthesized molecules found only in plants that are produced to protect the plant's cells. Phytonutrients primarily have antioxidant, free-radical scavenger and vital micronutrient

activity. These molecules, supplied through dietary supplementation, are found in mature plant tissues, and are most concentrated in seed coats and fruiting tissues surrounding the seed. In mammalian tissues, these molecules when supplied in the diet, are active in optimizing the biochemistry, immunology and physiology in the cellular micro-environment.

As used herein, the term "dioscorea complex" refers to an extract of dioscorea species (Mexican yam) providing a natural pre-cursor, dietary nutrient, diosgenin, a complex, six-ring, cyclic-carbon molecule that contains the molecular scaffold (perhydrocyclopentanophenanthrene) upon which mammalian adrenal and gonadal hormones are naturally synthesized. Providing this complex molecule in the diet can support optimal hormone balance, while maintaining normal physiological control mechanisms. This dietary supplement component has the potential to improve metabolic regulation of virtually every functioning cell in the body.

As used herein, the term "herbal extract" refers to phytochemicals that are produced in plant tissues and that can be extracted by water, polar, or petroleum solvents, and that have some degree of beneficial health or therapeutic activity. Most herbal agents can be toxic, especially when concentrated, but are generally safe when utilized in their more traditional manner in teas and poultices as a "folk medicinal for the treatment of disease and promotion of good health. As used herein, the term "herbal body-toning agent" refers to substances that have been observed by the inventors to reduce and reverse elastic tissue and collagen fiber damage caused by aging or sun-damage as evidenced by a restoration of skin turgor and elasticity which effectively reduces or eliminates wrinkles, sagging, hyperpigmentation and reversal of other undesirable elements of lost cosmetic appearance.

The carbohydrates included in the dietary supplement of the invention are available from a wide variety of natural and synthetic sources such as shrubs, trees, plants, yeasts, fungi, molds, gums, resins, starch and cellulose derivatives and natural mucin sources. Specifically, some of the natural sources include: (a) shrub or tree exudates which contain acacia, karaya, tragacanth, or ghatti; (b) marine gums which include agar, algin, or carrageenan; (c) seed gums which include guar, locust bean, or psyllium; (d) plant extracts which contain pectins or acetylated polymannose; (e) starch and cellulose derivatives such as hetastarch, carboxymethylcellulose, ethylcellulose, hydroxypropyl methylcellulose, methylcellulose, oxidized cellulose; and microbial gums which contain dextrans, xanthan. (Tyler et al., 1981) However, it should be recognized that the composition of the invention is not intended to be limited by the source from which the respective carbohydrates are obtained.

The saccharides of the invention can be found in nature as mono-, oligo- and/or polysaccharides. Thus, the compositions of the invention can contain the saccharides in their monomeric, oligomeric and/or polymeric forms. Table 3 below lists some of the known natural sources for the saccharides of the invention.

Table 3. Natural sources of saccharides.

Source Carbohydrate	Corresponding Saccharide(s)
gum tragacanth	galacturonic acid and sialic acid
guar gum	mannose and galactose (1:2 molar ratio)
rice or grain flour	glucose
LAREX B-1000 (Larch tree extract)	polyarabinogalactan
MANAPOL™ (aloe vera extract)	acetylated mannose based polymer
gum ghatti	arabinose, galactose, mannose, xylose, glucuronic acid (10:6:2:1:2 molar ratio)
starch	glucose
pectin	galacturonic acid
chondroitin sulfate	N-acetylgalactosamine
chitin	N-acetylglucosamine
acacia, gum arabic	arabinose, galactose, glucuronic acid
alginic acid	mannosyluronic acid, gulosyluronic acid
carrageenan	galactose, 3,6-anhydrogalactose
dextran	glucose
xanthan gum	glucose, mannose, glucuronic acid

It is well recognized in the art that the saccharides listed above with their corresponding source carbohydrates are present in particular amounts in nature as exemplified

by the indicated molar ratios for the saccharides in gum ghatti and guar gum. The relative amounts or ratios of saccharides in natural carbohydrates is readily determined using conventional extraction or analytical methods or can be obtained from literature sources commonly used in the art.

As used herein, the term "carbohydrate" is used interchangeably with the terms "saccharide", "polysaccharide", "oligosaccharide" and "sugar" the definitions of which are well known in the art of carbohydrate chemistry. Although the compositions of the invention are intended to include at least one of the eleven essential saccharides, it should be noted that the saccharides can be in the form of mono-, oligo- and/or polysaccharides, e.g. a composition containing gum tragacanth and guar gum will be considered as containing galacturonic acid, sialic acid, mannose and galactose. Therefore, by controlling the amount of particular gums in a given dietary supplement, one can control the amount of the respective saccharides in said dietary supplement.

Although the present invention includes the above cited eleven essential saccharides, it should be noted that other saccharides, nutritional compounds or biologically active or inert compounds can be included in the dietary supplement of the invention. Such other nutritional compounds include any one or more of phytonutrients, dioscorea complex, plant extracts, herbal extracts, plant parts, herbal components, vitamins or minerals. These nutritional compounds can be added to the dietary supplement of the invention, or they can be provided separately to a mammal being administered said dietary supplement. For example, a person receiving the glyconutrient-containing dosage form of the invention can also receive a phytonutrient in either the same or a separate dosage form. Inert compounds can include flavors, fillers, lubricants, buffers, gels, binders, excipients, carriers and/or other such compounds that facilitate the formulation or administration of the inventive dietary supplement. All of the glyconutrient-containing dietary supplement compositions of the invention, even those containing additional compounds, agents or other substances, can be obtained directly from MANNATECH™ (Coppell, TX).

Dioscorea complex is available from Ayusherbs (Japan) . When dioscorea complex is included in the dietary supplement of the invention, the ratio of dioscorea complex to total essential saccharide can range from about 0.0001/99.9999 to about 50/50 on a weight percent basis. In particular embodiments, the dioscorea complex to total essential saccharide ratio ranges from about 0.01-70/99.99-30 or about 10-40/90-60 or about 20/80.

Phytonutrients are available from a wide variety of manufacturing sources such as Cap-Tab (U.S.) or they can be added by freeze-drying and grinding ripe fruits and/or vegetables to form a powder which can then be added to or provided along with the dietary supplement of the invention. Such fruits and vegetables can be selected from all known fruits and vegetables but, in particular exemplary embodiments, include broccoli, brussel sprouts, cabbage, carrot, cauliflower, garlic, kale, onion, papaya, pineapple, tomato and turnip. These phytonutrients can be formulated in powder-containing caplet or capsule forms or in a base of gelatin and natural fruit fructose, optionally containing added flavors. When a phytonutrient is included in the dietary supplement of the invention, the ratio of total phytonutrient to total glyconutrient can range from about 0.001/99.999 to about 99.99/0.01 on a weight percent basis. As used herein, Phyto-1 refers to a dietary supplement comprising Glyco-1 (see Example 5), and freeze-dried raw fruits and vegetables. In particular embodiments, the phytonutrient to total glyconutrient ratio ranges from about 20-99/80-1 or about 50-95/50-5.

There are many plant and herbal extracts with suspected or demonstrated nutritional value which can promote good health and can be incorporated in or administered along with the dietary supplement of the invention. Such plant and herbal extracts can be obtained according to well known procedures for the extraction of substances, compounds or agents from plants or herbs. In particular embodiments, the dietary supplement of the present invention includes herbal or plant extracts of broccoli, brussel sprouts, cabbage, carrot, cauliflower, garlic, kale, onion, papaya, pineapple, tomato, asparagus, mushroom, parsnip, radish, and turnip. When a plant or herbal extract is included in the dietary supplement of the invention, the ratio of total extract (dry solids weight basis) to total glyconutrient can range from about 0.001-75/99.999-25 to about 10-90/90-10 on a weight percent basis.

Many different types of vitamins and minerals can be included in the dietary supplement of the invention. While a few vitamins and minerals of synthetic origin do possess nutritional value, particular embodiments of the dietary supplement herein contain nutritionally effective amounts of non-toxic vitamins and minerals obtained predominantly from natural sources. PROFILE™ is the tradename of a vitamin and mineral supplement used in the nutritional studies exemplified herein. This product, which can be obtained from MANNATECH™ (Coppell, TX), contains nutritionally effective amounts of the following vitamins and minerals: a) vitamins comprising A, B1, B12, B2, B6, beta carotene, bioflavanoids, biotin, C, choline, D, E, folic acid, inositol, K, niacinamide, para-aminobenzoic acid, and pantothenic acid; and b) minerals comprising boron, calcium, copper, GTF chromium, iodine, iron, magnesium, manganese, molybdenum, potassium, selenium, silicon,

vanadium, and zinc. These vitamins and minerals may be provided in nutritionally acceptable non-toxic forms.

By "nutritionally effective amount" is meant that amount which will provide a beneficial nutritional effect or response in a mammal. For example, as nutritional response to vitamin- and mineral-containing dietary supplements varies from mammal to mammal, it should be understood that nutritionally effective amounts of said vitamins and minerals will vary, respectively. Thus, while one mammal may require a particular profile of vitamins and minerals present in defined amounts, another mammal may require the same particular profile of vitamins and minerals present in different defined amounts.

Other compounds, agents and nutrients can also be included in the dietary supplement of the invention, such as, for example, cellulose, calcium carbonate, kola nut, kola nut extract, country mallow, Atlantic kelp, cayenne pepper, silica, stearic acid, amino acids, glycine, lysine, glutamic acid, arginine, calcium carbonate, orchic substances, boron citrate, chromium picolinate, essential fibers, essential oils, essential botanicals, essential enteric ecology and flora growth promoters, essential fatty acids, live probiotic flora, proteins and enzymes.

The dietary supplement of the invention has been prepared and administered to mammals in powdered, reconstitutable powder, liquid-solid suspension, liquid, capsule, tablet, caplet, lotion and cream dosage forms. It should be readily obvious to one of ordinary skill in the science of formulations that the present dietary supplement can also be formulated appropriately for irrigation, ophthalmic, otic, rectal, sublingual, transdermal, buccal, vaginal, or dermal administration. Thus, other dosage forms such as chewable candy bar, concentrate, drops, elixir, emulsion, film, gel, granule, chewing gum, jelly, oil, paste, pastille, pellet, shampoo, rinse, soap, sponge, suppository, swab, syrup, chewable gelatin form, or chewable tablet can be used.

Due to varying diets among people, the dietary supplement of the invention can be administered in a wide range of dosages and formulated in a wide range of dosage unit strengths. For example, for those people who are missing from their diet nine of the eleven essential saccharides, a dietary supplement containing those nine saccharides in nutritionally effective amounts can be formulated. As well, for those people whose bioabsorption of essential saccharides is extremely efficient, a dietary supplement formulation containing reduced amounts of essential saccharides can be prepared.

It should be noted that the dosage of the dietary supplement can also vary according to a particular ailment or disorder that a mammal is suffering from when taking the supplement. For example, a person suffering from chronic fatigue syndrome, or fibromyalgia, will generally require a dose different than an alcoholic who is trying to discontinue alcohol consumption in order to obtain a nutritional benefit. An appropriate dose of the dietary supplement can be readily determined by monitoring patient response, i.e., general health, to particular doses of the supplement. As well, when another agent such as a phytonutrient, plant extract, herbal extract and/or dioscorea complex is being administered to a mammal along with the present glyconutritional dietary supplement, the appropriate doses of the supplement and each of the agents can be readily determined in a like fashion by monitoring patient response, i.e. general health, to particular doses of each.

It is contemplated by the invention that the dietary supplement can be administered simultaneously or sequentially in one or a combination of dosage forms. While it is possible and even likely that the present dietary supplement will provide an immediate overall health benefit, such benefit may take days, weeks or months to materialize. Nonetheless, the present glyconutritional dietary supplement will provide a beneficial nutritional response in a mammal consuming it.

It is also contemplated that the dietary supplement of the invention can be administered simultaneously or sequentially along with at least one of a phytonutrient, an herbal extract, a plant extract, and a dioscorea complex. Particular embodiments wherein the dietary supplement is administered simultaneously with at least one of a phytonutrient, an herbal extract, a plant extract, and a dioscorea complex are exemplified in the following examples.

For the examples herein, the dietary supplement of the invention was administered as a powder-containing capsule. When the dietary supplement included a phytonutrient, it was administered as a caplet or gelatin form. When the dietary supplement included a dioscorea complex, it was administered as either a capsule or caplet. When the dietary supplement included a phytonutrient, a dioscorea complex and an herbal extract, it was administered as a caplet.

According to the capsule or caplet size and ingredients used in a given study exemplified herein, the dietary supplement was administered initially as follows. The indicated doses are based upon #1 sized capsules and 1000 - 1200 mg caplets.

SUPPLEMENT	DOSAGE
Glyco-1	2 capsules, 4x/day
Phyto-1	1 caplet, 4x/day
Glyco-1 with dioscorea complex	1 caplet, 4x/day
PROFILE™	1 tablet, 3x/day

As the exemplified studies proceeded, the doses of the supplements were modified according to patient response to a prior dosing regimen. For example, if a patient's overall health was not improving at the initial dose, the respective dose for one or more of the supplements was modified. It should be noted that the actual doses ultimately given to each patient in a study varied greatly from patient to patient as nutritional response varied. Generally, the dietary supplement and each of the other supplements was administered in the range of about 1 to about 12 capsules (or caplets or tablets) per day.

It is well documented that biochemical individuality exists among mammals and results in a very wide range of drug or food required to obtain a desirable health promoting effect. (Williams, R.; in Nutrition Against Disease, 1971). The amount of the above nutraceuticals typically utilized initially as a dietary supplement is indicated for conditions of compromised health. Energy level, stiffness, pain, discomfort, restful sleep, recovery from fatigue, and emotional status are used as nutritional benefit markers in determining a mammal's nutritional response to the dietary supplement and in determining whether or not an increase in dose is warranted. A reduction of health complaints or a reduction or elimination of the above parameters is used as a guide for the reduction of glyconutrient intake. Complicating factors in regard to the amount of glyconutrients required for a benefit include the differing quantitative needs that individual have for nutrients, the differences being due to genetics, biochemical balance, disease state, altered physiology, prior and current general nutrition, individual choice and the nutrient content of food eaten by individuals. A desirable response or improvement in health is obtained when the missing nutrient or nutrients is/are adequately supplied by the present dietary supplement. The human body defends, repairs, regenerates, regulates, and heals itself through gene-control and nutrition provides the resources to accomplish these tasks. The inventive dietary supplement herein contain glyconutrients no longer commonly found in the urban/suburban food chain and thus supply a more optimal

source of known and yet to be identified nutrients necessary for optimal biochemistry and physiology.

EXAMPLE 1

A suitable composition for a product according to the present invention is as follows: tragacanth gum (100 kg), a source of galacturonic acid and sialic acid (N-acetylneuraminic acid) is charged into a stainless steel ribbon blender and guar gum (10 kg), a source of mannose and galactose, is charged into the stainless steel ribbon blender. The mixture of tragacanth gum and guar gum is mixed for five (5) minutes. Then 250 grams of Aerosil 380™ (silica gel) is added to the mixture as a flowing agent and 200 kilograms of rice flour, a source of glucose, is added as a gluten-free filler. The mixture is then agitated for fifteen (15) minutes. Finally, 100 grams of calcium stearate is added to the mixture as a lubricant and the mixture is agitated for an additional three (3) minutes to generate a bulk powder. The powder is then encapsulated into size 1 gelatin capsules at a fill weight of 250 mg using a Model 8 (Elanco) capsule filling machine.

EXAMPLE 2

Another suitable composition for a product according to the present invention is as follows:

25 kilograms each of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, and xylose available from Florida Food Products as well as Aldrich Chemical Company and Sigma Chemical is charged into a stainless steel ribbon blender and mixed for five (5) minutes. Then 250 grams of Aerosil 380™ (silica gel) is added to the mixture as a flowing agent and 200 kilograms of rice flour, a source of glucose, is added as a gluten-free filler. The mixture is then agitated for fifteen (15) minutes. Finally, 100 grams of calcium stearate is added to the mixture as a lubricant and the mixture is agitated for an additional three (3) minutes to generate a bulk powder. The powder is then encapsulated into size #1 gelatin capsules at a fill weight of 250 mg using a Model 8 (Elanco) capsule filling machine.

EXAMPLE 3

Another suitable composition for a bulk product according to the present invention is as follows. This formulation can be prepared according to Example 2. The weight percentages indicated are based upon the final weight of the composition.

Percent by Weight	Ingredient	Approximate Density
20	Gum Tragacanth T/3	0.71 g/ml
20	Gum Ghatti No. 1	0.79 g/ml
40	arabinogalactan	0.20 g/ml
20	MANAPOL®	0.12 g/ml
	combined ingredients	0.30 g/ml

Gum tragacanth T/3 and Gum Ghatti No. 1 are both tree exudates that are available from AEP Colloids of Ballston Spa, New York. Arabinogalactan is obtained from the Larch tree and is available from North American Pharmacal of Norwalk, Connecticut. MANAPOL® is a freeze-dried aloe vera extract available from Carrington Laboratories (Irving, Texas).

EXAMPLE 4

Standardization Assay

The following assay describes a method for standardization of concentrations of sugars covered by this patent.

Standards: All carbohydrate standards are available from Aldrich Chemical Company, Milwaukee, Wisconsin.

Eluent: Deionized (DI) water having a resistance greater than or equal to about 17 MOhm.

Sample preparation: 2 ml of 2 N hydrofluoric acid are added to 10mg of sample to be analyzed in a screw-top, TEFLON lined 10 ml test tube. The sample is then incubated at 120° C for one hour to hydrolyze into monosaccharides. The excess reagent is removed under a stream of air and the sample resuspended in 1 ml of DI water.

HPLC Analysis: AOAC Official Methods of Analysis 977.20

EXAMPLE 5

The dietary supplement formulation of this example was prepared on large scale according to the above examples. This formulation, referred to as Glyco-1, includes the following ingredients in the amounts indicated. The weight percentage is based upon the weight of the final formulation containing all of the ingredients.

Ingredient	Weight Percent
MANAPOL® (aloe vera extract)	10
gum ghatti	10
gum tragacanth	10
glucosamine	10
corn starch	12
arabinogalactan	48

This composition was formulated into topical and oral preparations as indicated above.

EXAMPLE 6

Reduction of Medicine Induced Side-effects in

the Treatment of Attention-Deficit Hyperactivity Disorder

Manual 4th Ed. (DSM-IV) definitions for ADHD. One group consisted of five children whose parents had not placed them on methylphenidate (NO MED). The other 12 children in the study were receiving one of two different doses of methylphenidate: (a) six children received the normal prescribed dose (MED); and (b) six children received a reduced dose, i.e. below the normal prescribed dose (MED RED).

Assessment tools consisted of an ADHD rating scale for the DSM-IV symptoms; 18 items were rated on a scale of 0-3 for severity. Identical scales were constructed for the Oppositional Defiant Disorder (ODD) symptoms and the Conduct Disorder (CD) behaviors listed in DSM-IV. Both parents and teachers completed the above scales at each evaluation. In addition, parents completed a General Health Inventory for their children.

After all screening assessments were completed, all subjects had the glyconutritional product Glyco-1 added to their diets (1 capsule per 10 pounds of body weight for the first day and 1 capsule per 20 pounds of body weight for the remainder of the study). At week two, parent and teachers completed another rating series and the MED RED group had their medication reduced by half as per protocol. At week three, phytonutritionals (Phyto-1; 5 per day) were added to the dietary supplement procedure. The additional rating series were completed at weeks five and six.

The results indicated the Glyco-1 did not provide any further improvement in the ADHD symptomatology above that already obtained with the methylphenidate alone. However, a statistically significant reduction in the side-effects caused by the methylphenidate was obtained when Glyco-1 was administered to the subjects; therefore, an improvement in their overall general health was achieved.

EXAMPLE 7

Treatment of Alcoholics with Glyco-1

Glyco-1 capsules used in this study were prepared according to Example 6. The purpose of this study was to evaluate the effectiveness of dietary glyconutritional supplementation on the mood states and craving for alcohol in alcoholics. The study was conducted as follows.

Two groups of subjects were recruited from a local alcoholic support group in Little Rock, Arkansas: three recovering alcoholics and two practicing alcoholics. Each met the Diagnostic and Statistical Manual 4th Ed. (DSM-IV) criteria for alcohol dependency. In the

recovering group, abstinence varied from 2.5 years to six years and 11 months. For both groups, years of alcohol abuse ranged from 15 to 30 years and ages ranged from 33 to 62.

Assessment tools consisted of a self-rating scale of craving for alcohol which was scored from 0 to 9 and the Profile of Mood States (POMS). The POMS 65 items were divided into five scales: Cognitive, Depression, Energy, Anger/Temper, and Positive Outlook. These assessments were completed prior to taking glyconutritionals and again at the end of the five-week study.

Glyconutritionals were added to each subject's diet: 1 capsule per 10 pounds of body weight for the first day and thereafter 1 capsule per 20 pounds of body weight for the duration of the trial. No other interventions were introduced.

Results indicated that the mean initial alcohol craving of the five subjects had decreased in a statistically significant manner. Likewise, the results also indicated statistically significant improvements in the all of the measured mood states.

EXAMPLE 8

Treatment of various disorders with Glyconutrients

The following table summarizes the results obtained when patients were administered Glyco-1 either alone or in combination with one or more of Phyto-1, Glyco-1 with dioscorea and PROFILE™. Each patient was administered an initial dose Glyco-1 and any one or more of the respective supplements in the dosages indicated as follows:

SUPPLEMENT	DOSAGE
Glyco-1 (A)	2 capsules, 4x/day
Phyto-1 (B)	1 caplet, 4x/day
Glyco-1 with dioscorea complex (C)	1 caplet, 4x/day
PROFILE™ (D)	1 tablet, 3x/day

"E" indicates a topical hydrogel formulation comprising glyconutritionals

"F" indicates an oral dietary supplement comprising glyconutritionals and herbal extracts.

"E" indicates a topical hydrogel formulation comprising glyconutritionals

"F" indicates an oral dietary supplement comprising glyconutritionals and herbal extracts.

During each study, patient progress and nutritional or overall health response to administration of a given dietary supplement regimen was monitored. For those patients not responding well to initial doses, their dosing regimen was altered and their progress monitored again. It should be noted that in each of the cases, the Glyco-1 at an appropriate dose provided nutritionally effective amounts of the essential saccharide(s) necessary to promote good overall health in a given patient. That is, the glyconutrient-containing dietary supplement of the invention is not intended or professed to cure any of the disorders listed below. Rather, the dietary supplement provides a patient the necessary glyconutrients to permit a patient's own body to heal itself.

Table 4. Disorders treated by administration of glyconutrients alone or in combination with one or more of phytonutrients, dioscorea complex and vitamins and minerals.

DISORDER	NUTRITIONAL PRODUCTS ADMINISTERED	TREATMENT RESULTS
aging process or optimal health plan	A, B, C, D	decreased body fat; increased muscle mass and bone density; serum biochemistry altered to more healthy values
old stable strokes	A, B, C	restored sensory and muscular control
multiple sclerosis	A, B, C	restored sensory and muscular control
amyotrophic lateral sclerosis	A, B, C	restored sensory and muscular control
muscular dystrophy	A, B, C	restored sensory and muscular control
cerebral palsy	A, B, C	restored sensory and muscular control
macular degeneration	A, B, C	sight restorations

DISORDER	NUTRITIONAL PRODUCTS ADMINISTERED	TREATMENT RESULTS
seizures	A, B, C	reduction or elimination of allergies and infections; coordination, learning, memory and appearance improvements
Down's Syndrome	A, B, C	reduction or elimination of allergies & infections; coordination, learning, memory and appearance improvements
systemic combined immune deficiency syndrome	A, B, C	antibody and T-cell function restoration
Tay-Sachs	A, B, C	restoration of lost functions
retinitis pigmentosis	A, B, C	sight restoration
color blindness	A, B, C	can see color
Huntington's chorea	A, B, C	restoration or improvement of lost functions
Alzheimer's	A, B, C	restoration or improvement of lost functions
Parkinson's	A, B, C	restoration or improvement of lost functions
inflammatory polyneuropathy	A, B, C	restoration or improvement of lost functions
Closed head traumatic syndromes	A, B, C	restoration or improvement of lost functions
spinal cord injury	A, B, C	restoration or improvement of lost functions
ulcerative colitis	A, B, C	healed ulcers
Crohn's disease	A, B, C	healed ulcers
schizophrenia	A, B, C	improvements in functions
depression	A, B, C	improvements in functions
anxiety reactions	A, B, C	improvements in functions
compulsive disorders	A, B, C	improvements in functions
nervous tics	A, B, C	improvements in functions

DISORDER	NUTRITIONAL PRODUCTS ADMINISTERED	TREATMENT RESULTS
restless leg syndrome	A, B, C	improvements in functions
Tourette's syndrome	A, B, C	improvements in functions
autism	A, B, C	improvements in functions
Wegener's granulomatosis	A, B, C	restoration of tissue
Lupus E.	A, B	healing of lesions
Rheumatoid arthritis	A, B	relief of symptoms
thyroiditis	A, B	normalization of antinuclear antibodies
myesthenia gravis	A, B	normalization of antinuclear antibodies
diabetes mellitus	A, B	normalization of glucose and Hgb AIC; restoration of renal functions; healing of ulcers, elimination of infection; elevated lipids normalize; reduced insulin and glycomeds
osteoporosis	A, B	reduced pain increased bone density
alcoholism	A	reduction in craving
cocaine	A	reduction in craving
atherosclerosis	A, B	reduced total cholesterol, LDL, and triglycerides and increased HDL; improved patency of vessels and arrhythmia
idiopathic myocarditis (presumed viral origin)	A, B	increased ejection function; restoration of heart size; increased Coxsackievirus antibody levels; and reversal of heart failure
rheumatoid arthritis	A, B	elimination of pain, stiffness, fever, and swelling; restoration of scope of motion, strength and endurance

DISORDER	NUTRITIONAL PRODUCTS ADMINISTERED	TREATMENT RESULTS
degenerative arthritis	A, B	elimination of pain, stiffness, fever, and swelling; restoration of scope of motion, strength and endurance
traumatic arthritis	A, B	elimination of pain, stiffness, fever, and swelling; restoration of scope of motion, strength and endurance
juvenile arthritis	A, B	elimination of pain, stiffness, fever, and swelling; restoration of scope of motion, strength and endurance
asthma	A	elimination of shortness of breath and wheezing and improvement of pulmonary function
allergy - nasal, eyes, hay fever	A	elimination of itching, swelling, rash discomfort
silicon breast implant	A, B, C	reduction or elimination of symptoms
environmental toxin syndrome	A, B, C	reduction or elimination of symptoms
agent orange	A, B, C	reduction or elimination of symptoms
Gulf War syndrome	A, B, C	reduction or elimination of symptoms
Hepatitis B & C	A, C, D	normalization of liver enzymes and symptoms
influenza virus	A, C, D	prevention or amelioration; improvement of symptoms
common cold	A, C, D	prevention or amelioration; improvement of symptoms
AIDS	A, C, D	elimination of symptoms; m-RNA of HIV-1 is undetected; restored immune function
herpes	A, C, D	elimination of infestations

DISORDER	NUTRITIONAL PRODUCTS ADMINISTERED	TREATMENT RESULTS
warts	A, C, D	elimination of infestations
human papillovirus	A, C, D	elimination of infestations
otitis media (chronic or persistent)	A, C, D	elimination of symptoms and need for antibiotics
leukemia	A, B, C, D	correction of altered chromosomes
lymphomas	A, B, C, D	normalization of tissue biopsies
sarcomas (astrocytomas)	A, B, C, D	normalization of tissue biopsies
adenocarcinomas such as breast, prostate, ovarian, gastrointestinal and lung	A, B, C, D	elimination of metastasis and shrinkage of mass to undetectable level
profound introversion and female impotence	A, B, C, D	restoration of psychological interest and physiological sexual function in the elderly
pain, ulcers and coldness of extremities in diabetes, raynauds, frost-bite, snake-bite and atherosclerosis	A, C, E	restoration to intact, painless extremity and microvascular circulation
sun damaged skin, age damaged skin, and radiation damaged skin	A, C, E	lessening of pigmentation, wrinkles, and lost elasticity and restoration of dermis and epidermis
athletic performance	C, F	increased strength and endurance, delayed fatigue, facilitation of recovery in young and aging athletes

In summary, this invention pertains to the field of dietary supplements and nutritional support for promotion and maintenance of optimal good health. More specifically, the invention relates to compositions of carbohydrates as dietary supplements that are essential for the production of correctly structured and, therefore, properly functioning glycoproteins.

Science has recently shown that glycoproteins play a key role in all cellular communication. Many of the cytokines, i.e. cellular "words," do not function properly

without an attached glycosyl moiety. The body hydrolyzes complex polysaccharides such as plant carbohydrates into various monosugars and restructures them into oligosaccharides that are then used by the body to build the glycoproteins required by cytokines for cellular communication and, thus, for good health.

This invention will correct the problem caused by modern diets consisting of highly refined foods, from which many essential ingredients have been eliminated during processing, specifically sugars needed for correctly structured and properly functioning glycoproteins.

The above is a detailed description of particular embodiments of the invention. Those of skill in the art should, in light of the present disclosure, appreciate that obvious modifications of the embodiments disclosed herein can be made without departing from the spirit and scope of the invention. All of the embodiments disclosed herein can be made and executed without undue experimentation in light of the present disclosure. The full scope of the invention is set out in the disclosure and equivalent embodiments thereof. The specification should not be construed to unduly narrow the full scope of protection to which the present invention is entitled.

As used herein and unless otherwise indicated, the terms "a" and "an" are taken to mean "one", "at least one" or "one or more".

CLAIMS

What is claimed is:

1. A dietary supplement for providing nutritional product saccharides which are essential components of glycoproteins in a mammal, said dietary supplement comprising a nutritionally effective amount of at least one saccharide, in monomeric, oligomeric or polymeric and derivatized or underivatized form, selected from the group consisting of:

galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, xylose, arabinose, glucuronic acid, galacturonic acid, iduronic acid, arabinogalactan and acetylated mannose;

provided that:

1) when mannose is present alone, it is present in monomeric form; and

2) when acetylated mannose is present alone, it is present in monomeric form.

2. A dietary supplement for providing nutritional product saccharides which are essential components of glycoproteins in a mammal, said dietary supplement comprising a nutritionally effective amount of at least two saccharides, in monomeric, oligomeric or polymeric and derivatized or underivatized form, selected from the group consisting of:

galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, xylose, arabinose, glucuronic acid, galacturonic acid, iduronic acid, arabinogalactan, and acetylated mannose.

3. A dietary supplement for providing nutritional product saccharides which are essential components of glycoproteins in a mammal, said dietary supplement comprising a nutritionally effective amount of at least three saccharides, in monomeric, oligomeric or polymeric and derivatized or underivatized form, selected from the group consisting of:

galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, xylose, arabinose, glucuronic acid, galacturonic acid, iduronic acid, arabinogalactan, and acetylated mannose.

4. A dietary supplement for providing nutritional product saccharides which are essential components of glycoproteins in a mammal, said dietary supplement comprising a nutritionally

effective amount of at least four saccharides, in monomeric, oligomeric or polymeric and derivatized or underivatized form, selected from the group consisting of:

galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, xylose, arabinose, glucuronic acid, galacturonic acid, iduronic acid, arabinogalactan, and acetylated mannose.

5. A dietary supplement for providing nutritional product saccharides which are essential components of glycoproteins in a mammal, said dietary supplement comprising a nutritionally effective amount of at least five saccharides, in monomeric, oligomeric or polymeric and derivatized or underivatized form, selected from the group consisting of:

galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, xylose, arabinose, glucuronic acid, galacturonic acid, iduronic acid, arabinogalactan, and acetylated mannose.

6. A dietary supplement according to claim 2, 3, 4, or 5 wherein said saccharides are provided in oligomeric or polymeric forms as found in:

gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, aloe vera extract, gum ghatti, starch, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate, sucrose, acetylated polymannose, maltose, glucan, lentinan, mannan, levan, hemi-cellulose, inulin, fructan, and lactose.

7. A dietary supplement according to claim 1, 2, 3, 4, or 5 further comprising a nutritionally effective amount of dioscorea complex.

8. A dietary supplement according to claim 1, 2, 3, 4, or 5 further comprising a nutritionally effective amount of a blend consisting of ripened and freeze-dried and powdered raw fruits and vegetables.

9. A dietary supplement according to claim 8 further comprising nutritionally effective amounts of xanthines and herbal body-toning agents.

10. A dietary supplement according to claim 8, wherein said blend consisting of ripened and freeze-dried and powdered raw fruits and vegetables comprises:

broccoli, brussel sprouts, cabbage, carrot, cauliflower, garlic, kale, onion, papaya, pineapple, tomato and turnip.

11. A dietary supplement according to claim 7 further comprising a nutritionally effective amount of beta sitosterol.

12. A dietary supplement according to claim 1, 2, 3, 4, or 5 further comprising a nutritionally effective amount of melatonin.

13. A dietary supplement according to claim 1, 2, 3, 4, or 5 further comprising an effective amount of a saccharide bioabsorption aid.

14. A dietary supplement according to claim 13 wherein the bioabsorption aid comprises soy lecithin.

15. A dietary supplement according to claim 1, 2, 3, 4 or 5 further comprising nutritionally effective amounts of a dioscorea complex and a blend consisting of ripened and freeze-dried and powdered raw fruits and vegetables.

16. A dietary supplement according to claim 1, 2, 3, 4 or 5 further comprising nutritionally effective amounts of non-toxic vitamins and minerals.

17. A dietary supplement according to claim 16, wherein:

said vitamins comprise A, B1, B12, B2, B6, beta carotene, bioflavanoids, biotin, C, choline, D, E, folic acid, inositol, K, niacinamide, para-aminobenzoic acid, and panthothenic acid; and

said minerals comprise boron, calcium, copper, GTF chromium, iodine, iron, magnesium, manganese, molybdenum, potassium, selenium, silicon, vanadium, zinc.

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☒ Declaration Submitted with Initial Filing **OR** ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	013258.0172
First Named Inventor	McAnalley, Bill H.
COMPLETE IF KNOWN	
Application Number	/
Filing Date	
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

COMPOSITIONS OF PLANT CARBOHYDRATES AS DIETARY SUPPLEMENTS

(Title of the Invention)

the specification of which
☐ is attached hereto
OR
☒ was filed on (MM/DD/YYYY) 08/04/1997 as ~~United States Application Number or~~ PCT International Application Number PCT/US97/13379 and was amended on (MM/DD/YYYY) 08/11/1998 (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)
60/022,467	08/09/1996
60/030,317	11/01/1996
60/057,017	07/24/1997

☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)
PCT/US97/13379	08/04/1997	

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☐ Customer Number [ ] → *Place Customer Number Bar Code Label here*

OR

☒ Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
Randall C. Brown	31,213	Steven E. Ross	35,996
Rick Matos	40,082	Henry T. Crenshaw	37,805
Kenneth R. Glaser	24,015	Michael E. Martin	24,821
Richard L. Schwartz	27,227	George R. Schultz	35,674

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☐ Customer Number or Bar Code Label [ ] *OR* ☒ Correspondence address below

Name	Randall C. Brown				
Address	Akin, Gump, Strauss, Hauer & Feld, L.L.P.				
Address	P.O. Box 688				
City	Dallas	State	TX	ZIP	75313-0688
Country	U.S.	Telephone	214/969-4769	Fax	214/969-4343

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Bill H.	McAnalley

Inventor's Signature						Date	
Residence: City	Grand Prairie	State	TX	Country	U.S.	Citizenship	U.S.
Post Office Address	4921 Corn Valley						
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City	Grand Prairie	State	TX	ZIP	75052	Country	U.S.

☐ Additional inventors are being named on the ____ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto

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U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)
PCT/US97/13379	08/04/1997	

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☐ Customer Number [ ] → Place Customer Number Bar Code Label here
OR
☒ Registered practitioner(s) name/registration number listed below

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Rick Matos	40,082	Henry T. Crenshaw	37,805
Kenneth R. Glaser	24,015	Michael E. Martin	24,821
Richard L. Schwartz	27,227	George R. Schultz	35,674

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☐ Customer Number or Bar Code Label [ ] OR ☒ Correspondence address below

Name	Randall C. Brown				
Address	Akin, Gump, Strauss, Hauer & Feld, L.L.P.				
Address	P.O. Box 688				
City	Dallas	State	TX	ZIP	75313-0688
Country	U.S.	Telephone	214/969-4769	Fax	214/969-4343

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Bill H.	McAnally

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City	Grand Prairie	State	TX	ZIP	75052	Country	U.S.

☐ Additional inventors are being named on the ___ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto

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ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 1 of 2

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
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H. Reginald			McDaniel				
Inventor's Signature	H. Reginald McDaniel				Date	2/8/99	
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Post Office Address							
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Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
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Post Office Address	2911 Old Mill Run TX						
Post Office Address							
City	Grapevine	State TX	ZIP 76051	Country U.S.			

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
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Eileen P.			Vennum				
Inventor's Signature	Eileen P. Vennum				Date	8 Feb 99	
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Post Office Address	2229 N. Westfield TX						
Post Office Address							
City	Grand Prairie	State TX	ZIP 75050	Country U.S.			

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DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 2 of 2

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
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William C.		Fioretti					
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Post Office Address							
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Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])		Family Name or Surname					
Inventor's Signature						**Date**	
Residence: City		**State**		**Country**		**Citizenship**	
Post Office Address							
Post Office Address							
City		**State**		**ZIP**		**Country**	

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])		Family Name or Surname					
Inventor's Signature						**Date**	
Residence: City		**State**		**Country**		**Citizenship**	
Post Office Address							
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